

# ***NEWS RELEASE***

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## ***OFFICE OF THE UNITED STATES ATTORNEY SOUTHERN DISTRICT OF CALIFORNIA San Diego, California***

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***For Immediate Release***

### **NEWS RELEASE SUMMARY** - November 5, 2007

The United States Attorney's Office announced that Michael J. Ellis, the founder and former president of San Diego-based corporation Metabolife International, Inc., pled guilty today in federal court in San Diego before United States District Judge Napoleon A. Jones, Jr. to making false statements to the United States Food and Drug Administration ("FDA").

In connection with the guilty plea, Ellis' attorney told the Court that in February 1999, Ellis and his corporation – through a retained law firm – sent a letter to the FDA stating that Metabolife had a "claims free history." Ellis was aware at the time, however, that this statement was false. He also knew that the FDA would likely rely on Metabolife's statements regarding its consumer complaint history in the FDA's proceedings concerning regulation of ephedra-based supplements.

In 2002, Metabolife turned over to the FDA and then to the Department of Justice reports of more than 10,000 ephedra-related adverse events that the company had previously withheld. It was as a result of these reports and further investigation that on July 22, 2004, Ellis and Metabolife were indicted for making false statements to the FDA.

At the time Ellis submitted this false claim to the FDA, the agency was considering whether to regulate ephedra products more stringently. In particular, in 1997, the FDA had proposed a rule that would have deemed supplements containing 8 mg or more of ephedrine alkaloids to be “adulterated” and prohibited combining ephedra and caffeine – as in Metabolite’s signature product, Metabolife 356. The proposed rule would also have required stricter labeling of ephedra supplements requiring that ephedra labels warn that exceeding the recommended dosage “may result in heart attack, stroke, seizure, or death.” The FDA ultimately banned ephedra-containing dietary supplements as posing an unreasonable risk to consumers. On August 17, 2006, the Tenth Circuit Court of Appeals upheld the FDA's ban of ephedra, a ban which remains in effect.

Metabolife was formerly one of the largest retailers of dietary supplements in the United States, based largely on sales of its ephedra-based product, Metabolife 356. Following the indictment of Ellis and Metabolife, the FDA’s ban on ephedra, falling sales, and numerous personal injury legal claims related to Metabolife 356, Metabolife filed for Chapter 11 bankruptcy in 2005.

“The FDA depends on truthful information to make informed choices so they can fully and effectively protect the public health. The FDA’s Office of Criminal Investigations will aggressively investigate and pursue those who hamper the FDA’s ability to protect consumers by providing false and misleading information,” said Dan Henson, Special Agent in Charge, FDA Office of Criminal Investigations, Los Angeles Field Office.

“This investigation is a great example of how agencies worked together in pursuit of one of the nation's leading producers of ephedra products that misrepresented its products to drug regulators, lawmakers, and consumers,” said Acting Assistant Special Agent in Charge, Aimee Schabilion, IRS-Criminal Investigation, Los Angeles Field Office. “IRS-Criminal Investigation will continue to support efforts to dismantle organizations who put the public's health at risk.”

The defendants are scheduled to be sentenced on January 28, 2008, at 8:15 a.m.

**DEFENDANTS**

**Case Number: 03 CR 1088-J**

Metabolife International, Inc.  
San Diego, CA

Michael J. Ellis

**SUMMARY OF CHARGES AND MAXIMUM PENALTIES**

Making False Statements to the Food and Drug Administration in violation of  
Title 18, United States Code, Section 1001

Maximum penalties: five years in prison and a fine not to exceed \$250,000.

**PARTICIPATING AGENCIES**

Food and Drug Administration, Office of Criminal Investigation  
Internal Revenue Service, Criminal Investigation Division